REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated June 27, 2007 are respectfully requested.

I. Amendments to the Claims

Claims 1 and 8 have been amended to recite a homology of 90%, rather than 80%, and to include the language "and does not contain substitutions or alterations that significantly affect activity."

Support for the amendment can be found, for example, at ¶ [0037].

No new matter has been added.

II. Rejections Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1, 3, 4, 6, 8, 10, and 11 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement for the use of polypeptides other than those defined by SEQ ID NOs: 2 and 3.

The rejection is traversed.

A. Legal Standard for Enablement

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. A patent may be enabling even though some experimentation is necessary. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217 (Fed. Cir. 1988).

B. Argument

The instant claims are directed to a method of increasing the IL-10/IL-12 blood ratio in a human subject suffering from multiple sclerosis and to a method of inhibiting progression of multiple sclerosis in a human subject diagnosed with multiple sclerosis, by administering a certain dose of interferon-tau.

Interferon-tau has been studied and written about in the scientific literature for twenty years (see background section of Applicants' specification). Numerous interferon-tau protein sequences are known in the art and reported in GenBank (see paragraph [0036] of Applicants' specification). Thus, a skilled artisan can easily identify interferon-tau proteins.

The claim as amended recites "orally administering an interferon-tau protein . . . wherein said interferon-tau protein has a sequence having at least 90% sequence identity to SEQ ID NO:2 and does not contain substitutions or alterations that significantly affect activity . . ." Thus the subject protein is an *interferon-tau* protein with homology to a particular interferon-tau protein sequence (i.e., SEQ ID NO: 2) not *any* protein with homology to a particular interferon-tau protein sequence. The Examiner's assertion that "the claims read on the administration of many potential *non-IFN-τ polypeptides*," (emphasis added)" is contrary to the explicit language of the claims. Thus the rejection appears to ignore the claim language.

In the interest of advancing prosecution, Applicants have limited the homology recited in independent claims 1 and 8 to 90% and required that the protein does not contain substitutions or alterations that significantly affect activity. The subject protein is now defined as:

1) An interferon-tau, which is a recognized group of inteferons,
2) Having 90% homology to a particular interferon-tau, and
3) Not containing substitutions or alterations that significantly affect activity.

In view of the amendments and arguments, Applicants submit that that the specification provides more than adequate support for the claimed invention. However, in the event that the amendment does not overcome the rejection, Applicants request that the Examiner explain exactly how the subject protein could be interpreted to read on a *non-interferon-tau protein* in view of the claim language.

In view of the foregoing remarks and amendments, Application respectfully request withdrawal of the rejection.

III. Rejections Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 1, 3, 4, 6, 8, 10, and 11 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description for the use of polypeptides other than those defined by SEQ ID NOs: 2 and 3.

The rejection is traversed.

A. Legal Standard for Written Description

According to the M.P.E.P. § 2163.02, the objective standard for determining compliance with the written description requirement is "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed."

B. Argument

It is apparently the Examiner's position that since the specification does not describe any polypeptides that are less than 100% identical to SEQ ID NOs: 2 or 3 or regions or residues of these sequences that can be modified, the specification does not provide adequate written description for the claimed methods.

Interferon-tau is well characterized in the scientific literature, including structure/function studies. Interferon-tau is described in the specification (e.g., ¶¶ [0036] and [0037]) and exemplary polypeptide sequences are provided (i.e., SEQ ID NOs: 2 and 3). The specification refers to substitutions and alterations that do not significantly affect activity.

Claims 1 and 8 require that the subject protein is an *interferon-tau*, specify 90% homology, and required that the protein does not contain substitutions or alterations that significantly affect activity. The Examiners assertion that the "claims are drawn to administration of *any polypeptide* sequence that is 80% identical to SEQ ID NO: 2," (page 5, near middle; emphasis added) ignores the explicit language of the claim and description in the specification. The subject proteins are unambiguously *interferon-tau proteins*, which are a subset of interferons known in the art.

As above, in the event that the amendment does not overcome the rejection, Applicants request that the Examiner explain exactly how the subject protein could be interpreted to read on *any polypeptide*, when the claim language explicitly requires the polypeptide to be an *interferon-tau* protein.

Application respectfully request withdrawal of the rejection.

IV. Rejections Under 35 U.S.C. § 103

Claims 1, 3, 4, 6, 8, 10, and 11 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Soos et al. (WO 97/033607, "Soos"), in view of Boxel-Dezaire et al. (Ann. Neurol., 45:695-703 (1999), "Boxel-Dezaire"), and further in view of Petereit et al. (*J. Neurol. Sci.*, 206:209-214 (2003), "Petereit"). Reconsideration of the rejection is respectfully requested.

Summaries of the present claims and of the cited art are provided in Applicants' response submitted July 24, 2006.

The rejection is traversed.

A. Legal Standard for Obviousness

According to the MPEP § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations." While this standard may have been modified by *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007), the underlying principles still apply.

B. Argument

The present obviousness rejection is legally insufficient on its face. First, the Examiner has not identified each and every claim limitation in the prior art, particularly with respect to oral administration at the presently claimed dose of greater than about 5 x 10^8 Units/day. Second, the Examiner is incorrect in stating that a prior art disclosure

must teach away from an invention, in order to avoid an obviousness rejection (Office Action of June 27, 2007, top of page 7).

Moreover, the Examiner's reliance on *In re Aller, Lacey, and Hall*, 220 F2d 454, 105 USPQ 233, 235 (C.C.P.A. 1955) is misplaced (*Id.*). Indeed the court in *Aller*, found that "it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification." 105 USPQ 233, 235. However, the court continued that, ". . . changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result . . ." *Id.*

In the present case, the administration of a dose of interferon-tau greater than contemplated by Soos et al. (WO 97/033607) resulted in significantly increased IL-10, compared to lower doses. In particular, patients receiving 1.8×10^8 units IFN-τ (Group III) demonstrated significantly higher levels (at high as 3-fold) of serum IL-10 than patients receiving only 6×10^7 Units (Group II). These results are shown in Figure 4D.

From such data, it is apparent that a dose of IFN-τ greater than that contemplated by the reference provides superior therapeutic results. In the pharmaceutical filed, an improvement in clinical outcome is clearly a significant advantage in real-world terms and was a surprising result in view of the prior art. The Examiner is further directed to review the Declaration of Norman Kachuck, filed with the previous response. The Declaration provides additional objective evidence for unexpected results.

In view of these remarks, Applicants submit that the present claims are non-obvious in view of the cited references because (i) the prior art does not disclose each and every claim limitation, and (ii) the present method provides surprising results.

Withdrawal of the rejection under 35 U.S.C. §103 is respectfully requested.

V. Double-Patenting Rejections

Claims 1, 3, 4, 6, 8, 10, and 11 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1, 17, and 18 of co-pending Application Serial No. 11/112,369.

Enclosed herewith is an executed Terminal Disclaimer filed in accordance with C.F.R. §1.321(b) and (c) which disclaims the terminal portion of any patent issuing on the

instant application that extends beyond the of any patent that issues from application no. Application Serial No. 11/112,369.

The applicants submit that Terminal Disclaimer overcomes the rejection for obviousness-type double patenting and withdrawal of the rejection is respectfully requested.

VI. Conclusion

In view of the foregoing remarks and amendments, the claims pending in the application comply with the requirements of 35 U.S.C. § 112 and patentably define over the applied art. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 838-4328.

Respectfully submitted,
Perkins Coie LLP

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